

App. No. 10/600,061
Reply to Office Action of April 28, 2005

REMARKS/ARGUMENTS

Claims 1-17 remain in this application. The following issues are outstanding in the Office Action mailed April 28, 2005:

1. Claims 1, 8, 10 and 11 were objected to because of informalities;
2. Claims 1-7, 9, 10 and 12-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,412,982 ("Hunt et al.") in view of U.S. Patent No. 4,997,425 ("Shioya et al."); and
3. Claims 8 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. in view of Shioya et al. as applied to claims 1-7, 9, 10 and 12-17, and further in view of U.S. Patent No. 6,252,129 ("Coffee").

Each of these will be addressed in turn.

App. No. 10/600,061
Reply to Office Action of April 28, 2005

1. Objection to Claims 1, 8, 10 and 11

With respect to Claims 1, and 8, the phrase in Claim 8 "wherein said porous pad is formed by spraying a nontoxic chemical substance" was found to be inconsistent with the phrase in Claim 1, "having at least a partial outer surface and an inner body". The Examiner required further explanation and/or modification regarding these claims.

With respect to Claim 8, Applicants submit that it is possible for a porous pad to have both at least a partial outer surface and an inner body wherein the porous pad is formed by spraying a nontoxic chemical substance into the wound. In particular, Applicants refer to paragraphs [0057] through [0059] for example. When the nontoxic chemical substance is sprayed into the wound bed, for example, the chemical substance is under pressure such that gas is expelled from the chemical substance, which leads to expansion of the chemical substance. Because the surface of the wound acts as a restrictive boundary during this expansion, the substance will expand against the dimensions of the wound, and after reaching the boundary, will expand away from the wound, thereby forming at least a "partial outer surface" adjacent the wound, and inherently an inner body.

So, the Examiner is correct in noting that the chemical substance is sprayed out in a uniform *instantaneous* state. But immediately thereafter the chemical reaction begins, and the substance begins to expand as set forth in the specification. The properties of the substance against the wound will be different than the properties where limitless expansion is possible.

The same applies for the Examiner's objection to Claim 11 ("wherein said pad is formed by spraying a nontoxic chemical substance") and Claim 10 ("having at least a partial outer surface and an inner body"). One of skill in the art will know that the properties of the foam

App. No. 10/600,061
Reply to Office Action of April 28, 2005

formed after the chemical reaction of the nontoxic chemical substance may be affected and controlled by restricting the boundaries of expansion of the chemical substance, such as against a wound.

With respect to Claim 10, the Examiner noted the precise meaning of "material modifications to enhance biocompatibility" in line 4 of Claim 10 is unclear. Applicants refer the Examiner, for example, to paragraph [0053], which describes a material modification "forms a tissue compatible lubricious surface that is growth factor impregnated or is a molecular graft" and to Fig. 12. In addition, Applicants refer the Examiner to paragraph [0054] "with healing compatible micropores 207 of approximately 100 microns or less." Applicants respectfully submit that these examples, in addition to other examples in the specification, are sufficient to establish a precise meaning to the term "material modifications to enhance biocompatibility" in Claim 10.

The undersigned invites the Examiner to contact him regarding the meaning of this term should the Examiner disagree with Applicants present submissions. Withdrawal of these objections is respectfully requested in view of the comments above.

2. Rejection of Claims 1-7, 9, 10 and 12-17 under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. in view of Shioya et al.

The Examiner applied Hunt for teaching a porous pad that is permeable to liquids and is held in place by a surgical drape with adhesive providing a seal the pad, and also a vacuum canister for collecting drainage fluid that is sucked from the wound via a suction pump and connected to the porous pad through a drainage tube. Hunt did not teach an outer surface with

App. No. 10/600,061
Reply to Office Action of April 28, 2005

pores of a first size contacting the wound or a pad with an inner body with pores of a second average size. The Examiner applied Shioya for teaching a dressing with an outer surface layer superimposed on an inner sponge layer, with the outer layer containing pores of an average pore size less than the average pore size of pores in the inner sponge layer. Shioya was also cited for teaching the first average size pore is no more than 20 microns to prevent foreign bacteria from invading the wound, and that the second pore size in the outer layer is in the range of 20 to 500 microns because a pore size below 20 microns results in poor development of tissue and insufficient absorption of exudates, both of which are critical as the outer layer is contacting the wound surface, and a pore size larger than 500 microns may result in inadequate adhesiveness to the wound surface to allow the exudates to remain (Col. 4, lines 11-18). The Examiner concluded it would be obvious to modify the dressing of Hunt to include the second pore size in its wound-contacting surface to foster proper development of new healthy tissue and ensure appropriate adhesiveness to the wound surface as taught by Shioya.

Applicants respectfully traverse this rejection. Specifically, Shioya teaches a first layer to be placed on the wound surface having pores of 20 to 500 microns, and a second layer *remote from the wound surface* having pores not more than 20 microns, therein having an average pore size *at best equal* to the *smallest* pores of the first layer of Shioya, and more likely, *smaller* than the pore size of the first layer (i.e. wound surface). (See Col. 6, lines 50-67). This is directly opposite of what is claimed in Claim 1, which recites the inner body (e.g. remote from the wound surface) "having pores therein of a second average size, wherein said second average size is *greater* than said first average size". (Emphasis added). Claim 10 likewise contains the same language.

App. No. 10/600,061
Reply to Office Action of April 28, 2005

Accordingly, combining Shioya with Hunt would fail to yield the invention of independent Claims 1 and 10, much less teach, suggest or motivate one of skill in the art to reach the inventions of independent Claims 1 and 10 inasmuch as Shioya *specifically teaches the opposite* of the invention of these Claims. Claims 2-7 and 9 depend on Claim 1, which is allowable in view of the reasons stated above. Likewise, Claims 12-17 depend on either Claim 1 or Claim 10, which are allowable for the same reasons. As a result, these Claims are all submitted to be allowable over the art made of record, and action towards that end is respectfully requested.

3. Rejection of Claims 8 and 11 under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. in view of Shioya et al. as applied to claims 1-7, 9, 10 and 12-17, and further in view of Coffee.

Claim 8 depends on Claim 1, which is allowable in view of the comments above. Claim 11 depends on Claim 10, which is allowable for the same reason. Accordingly, Claims 8 and 11 are submitted to be allowable over the art made of record, and action towards that end is respectfully requested.

App. No. 10/600,061
Reply to Office Action of April 28, 2005

SUMMARY

Believing it has addressed all matters raised by the Examiner's November 19, 2003 Office Action, Applicants respectfully request timely action on the merits. No fees are believed to be required for the amendment. Nevertheless, the Commissioner is permitted to deduct or credit any fees that may be required from Kinetic Concept Inc. Deposit Account No. 500-326.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Applicants respectfully request favorable consideration.

Respectfully submitted,



Robert W. Mason
Reg. No. 42,848
Attorney for the Applicant

KINETIC CONCEPTS, INC.
P.O. Box 659508
San Antonio, Texas 78265-9508
TEL: (210) 255-6271
FAX: (210) 255-6969